



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JAN 29 2004

5961 '04 FEB -2 19:49

Beth Rosenshein  
15149 SE 48th Dr.  
Bellevue, WA 98006

Re: Docket No. 2003P-0357/CP1

Dear Ms. Rosenshein:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on August 1, 2003. Your petition requests that the Agency update the labeling for Premarin tablets to: (1) recognize decreased levels of testosterone with oral estrogen use and (2) list all known active components of Premarin.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

2003P-0357

LET 1